

THE UNITED STATES PATENT AND TRADEMARK OFFICE

TFW

Application of:

CURTISS III et al

Serial No.:

10/620,777

Art Unit: 1645

Filed:

July 15, 2003

Examiner:

Entitled:

RECOMBINANT BACTERIAL SYSTEM WITH

ENVIRONMENTALLY LIMITED VIABILITY

Attorney Docket No.: MEG-207.1 US-1

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Sir:

Transmitted herewith are: [X] an Information Disclosure Statement (8 pages), with a modified Form 1449 (6 pages); [X] a return receipt postcard, to be filed in the above-identified patent application.

FEE FOR ADDITIONAL CLAIMS

[X] A fee for additional claims is not required.

[] A fee for additional claims is required. The additional fee has been calculated as shown below:

	CLAIMS REMAINING	HIGHEST NUMBER	NUMBER OF EXCESS	RATE	FEES DUE		
	AFTER AMENDMENT	PREVIOUSLY PAID FOR	CLAIMS				
TOTAL CLAIMS	=		<u>0</u>	<u>\$50</u>	= 0.00		
INDEPENDENT		, 11	<u>0</u>	<u>\$200</u>	= 0.00		
FIRST INTRODUCTION OF MULT. DEPENDENT CLAIM \$360 = 0.00							
TOTAL FEES DU	TOTAL FEES DUE $= 00.00$						

PAYMENT OF ADDITIONAL FEES

[]	A check in the amount of \$ in payment of the fee for additional claims is transmitted herewith
[]	Please charge \$ to Deposit Account No. 50-0268 in payment of the fee for additional claims. A duplicate copy of this transmittal letter is transmitted herewith.

[]	A check including the amount of \$in payment of the fee for the submission of an Information Disclosure Statement is transmitted herewith.
[X]	The Commissioner is hereby authorized to charge payment of any additional fees required under 37 CFR 1.16 or 1.17 in connection with the paper(s) transmitted herewith, or to credit any overpayment of same, to Deposit Account No. 50-0268. A duplicate copy of this transmittal letter is transmitted herewith.
PETI	TION FOR EXTENSION OF TIME
[]	Extension is requested under 37 CFR 1.136(a), and the following extension fee is applicable for the Response filed herewith: [] \$120.00 for response within first month pursuant to 37 CFR 1.17(a)(1); [] \$450.00 for response within second month pursuant to 37 CFR 1.17(a)(2); [] \$1,020.00 for response within third month pursuant to 37 CFR 1.17(a)(3); [] \$1590.00 for response within fourth month pursuant to 37 CFR 1.17(a)(4); [] \$2160.00 for response within fifth month pursuant to 37 CFR 1.17(a)(5).
[]	A check including the amount of [] \$120.00 [] \$450.00 [] \$1,020.00 [] \$1590.00 [] \$2160.00 in payment of the extension fee is transmitted herewith.
[X]	The Commissioner is hereby authorized to charge payment of any additional fees required in connection with the paper(s) transmitted herewith, or to credit any overpayment of same, to Deposit Account No. 50-0268. A duplicate of this transmittal letter is submitted herewith.
	Respectfully submitted,
•	Respectfully submitted, Mill Wash.
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Mail in	by certify that this correspondence is being deposited with the United States Postal Service as First Class in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, 1313-1450 on the date indicated below:
	January 28, 2005 Keep & Aten
	Date Nasim G. Memon



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INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98

Dear Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicants submit this Information Disclosure Statement pursuant to 37 C.F.R. §§ 1.97 and 1.98 in the above-identified application for consideration by the Patent Office. This application is a Continuation of U.S. patent application Serial Number 08/761,769 filed on December 6, 1996. The 769 patent application is a Continuation In Part of patent application 08/473,789 filed on June 7, 1995.

A modified Form PTO-1449 listing the cited documents is also enclosed. Copies of all these cited references have been provided to the USPTO in the above-mentioned patent applications. This Statement is being submitted before the first Office Action on the merits. Pursuant to 37 C.F.R. § 1.97(b)(3), no fee is believed to be required with this submission.

US Patents

US 4,190,495; issued February 26, 1980, Curtiss;

US 4,968,619; issued November 6, 1990, Curtiss;

US 5,190,931; issued March 2, 1993, Inouye;

US 5,681,745; issued October 28, 1997, Szafranski et al; and

US 5,702,916; issued December 30, 1997, Molin, et al.

Foreign Patent Documents:

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Other Documents - Non-Patent Literature - Publications:

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Control of the Major Escherichia coli Cold Shock Promoter cspA", <u>Appl. Environ. Micro.</u>, 62(4):1444-1447 (1996)

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Applicants do not intend to represent that any of the documents listed herein is material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicants respectfully request that this list of documents herein be considered and made of record in this application.

Respectfully submitted,

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Michael R. Wesolowski, Reg. No. 50,944

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CERTIFICATE OF MAILING

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January 28, 2005

Date

Nasim G. Memor

Modified FORM PTO-1449	ATTY. DOCKET NO. MEG-207.1 US-1	SERIAL NO. 10/620,777
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	APPLICANT Roy CURTISS	SIII
Sheet 1 of 6	FILING DATE July 15, 2003	GROUP 1645

REFERENCE DESIGNATION U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4,190,495	2/26/80	Curtiss			
	AB	4,968,619	11/6/90	Curtiss			
	AC	5,190,931	3/2/93	Inouye			
	AD	5,681,745	10/28/97	Szafranski, et al.			
	AE	5,702,916	12/30/97	Molin, et al.			
	AF						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	TRANSL YES	ATION ON
A	AG	EP 0381706 B1	4/26/1995	Curtiss				
1	AH							

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

 AI	Barrett, Textbook of Immunology, Fourth Edition, (C. V. Mosby Co., St. Louis, MO, 1983)
AJ	Bienkowska-Szewczyk et al., "The R Gene Product of Bacteriophage λ", Mol. Gen Genet., 184:111-114 (1981)
AK	Bochner et al., "Positive Selection for Loss of Tetracycline Resistance", <u>J. Bacteriol.</u> ,143:926 (1980)
 AL	Brosius, "Plasmid Vectors for the Selection of Promoters", Gene, 27:151-160 (1984)
AM	Cardenas and Clements, "Oral Immunization Using Live Attenuated Salmonella spp. as Carriers of Foreign Antigens", Clinical Micro. Rev., 5(3):328-342 (1992)
AN	Cardineau and Curtiss, "Nucleotide Sequence of the asd Gene of <i>Streptococcus mutans</i> , J. Bio. Chem., 262:3344-3353 (1987)
AO	Chatfield et al., "Construction of a Genetically Defined Salmonella typhi Mutant for the Engineering of a Candidate Oral Typhoid-Tetanus Vaccine", Vaccine, 10:53-60 (1992)
AP	Chatfield et al., "The Development of Oral Vaccines Based on Live Attenuated Salmonella Strains", FEMS Immunol. Med. Microbiol., 7:1-7 (1993)
AQ	Christie, et al., "Synthetic Sites for Transcription Termination and a Functional Comparison with Tryptophan Operon Termination Sites <i>In Vitro</i> ", <u>Proc. Natl. Acad. Sci. USA</u> , 78:4180-4184 (1981)

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	AR	Clements, "Use of Attenuated Mutants of Salmonella as Carriers for Delivery of Heterologous Antigens to the Secretory Immune System", Pathol. Immunopathol. Res., 6:137-146 (1987)
	AS	Cornelis, "Yersiniae, Finely Tuned Pathogens", Molecular Biology of Bacterial Infections (Cambridge University Press, Cambridge, 1992)
	AT	Curtiss, III. "The Release of Genetically-Engineered Microorganisms", <u>Proceedings of the First International Conference on the Release of Genetically-Engineered Microorganisms</u> (Sussman et al. editors., Academic Press, pp. 7-19, 1988.
	AU	Curtiss, "Genetic Manipulation of Microorganisms: Potential Benefits and Biohazards", Ann. Rev., 30:507-533 (1976)
	AV	Curtiss et al., "Research on Bacterial Conjugation with Mini-Cells and Minicell-Producing E. Coli Strains", Microbial Drug Resistance, 3:169-183 (1982)
	AW	Curtiss and Kelly, "Salmonella Typhimurium Deletion Mutants Laking Adenylate Cyclase and Cyclic AMP Receptor Protein are Avirulent and Immunogenic", Infect. Imm., 55:3035-3043 (1987)
	AX	Curtiss et al., "Chromosomal Aberrations associated with Mutations to Bacteriophage Resistance in <i>Escherichia Coli</i> ", J. Bacteriol., 89:28-40 (1965)
	AY	Curtiss et al., "Avirulent Salmonella Expressing Virulence Antigens from other Pathogens for Use as Orally Administered Vaccines", Virulence Mechanisms Of Bacterial Pathogens (Roth, American Society for Microbiology, Washington, D.C., 1988) pages 311-328
	AZ	Curtiss et al., "Recombinant Salmonella Vectors in Vaccine Development", <u>Dev. Biol. Stand.</u> , 82:23-33 (1994)
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	ВВ	Curtiss et al., "Selective Delivery of Antigens by Recombinant Bacteria", <u>Curr. Topics Micro.</u> <u>Immun.</u> , 46:35-49 (1989)
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BP	Germanier and Furer, "Immunity in Experimental Salmonelosis", Infect. Immun., 4:663-73 (1971)
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СН	Kelly et al., "Characterization And Protective Properties Of Attenuated Mutants Of Salmonella choleraesuis", Infect. Immun., 60:4881-4890 (1992)
CI	Kingsbury et al., "Temperature-Sensitive Mutants for the Replication of Plasmids in <i>Escherichia coli:</i> Requirement for Deoxyribonucleic Acid Polymerase I in the Replication of the Plasmid CoIE1", J. Bacteriol., 114:1116-1124 (1973)
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CK	Kushner, "Construction of Versatile Low-Copy-Number Vectors for Cloning, Sequencing and Gene Expression in <i>Escherichia coli</i> ", Gene, 100:195-199 (1990)
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CN	Lugtenberg et al., "Temperature-Sensitive Mutant of <i>Escherichia coli</i> K-12 with an Impaired D-Alanine: D-Alanine Ligase", <u>J. Bacteriol.</u> , 113:96-104 (1973)
СО	McGhee and Mestecky, "The Secretory Immune System", <u>Ann. N.Y. Acad. Sci.</u> , Volume 409 (1983)
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CR	Miller and Mekalanos, "A Novel Suicide Vector and its Use in Construction of Insertion Mutations: Osmoregulation of Outer Membrane Proteins and Virulence Determinants in <i>Vibrio choleae</i> requires <i>tox</i> R", <u>J. Bacteriol.</u> , 170:2575-2583 (1988)
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СТ	Miyakawa et al., "Cell Wall Peptidoglycan Mutants of <i>Escherichia coli</i> K-12: Existence of Two Clusters of Genes, <i>mra</i> And <i>mrb</i> , For Cell Wall Peptidoglycan Biosynthesis", <u>J. Bacteriol.</u> , 112:950 (1972)
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CZ	Neidhardt et al., "The Genetics and Regulation of Heat-Shock Proteins", <u>Annu. Rev. Genet.</u> , 18:295-329 (1984)
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DO	Rodriguez and Denhardt, eds., <u>Vectors: A Survey Of Molecular Cloning Vectors And Their Uses</u> (Butterworths, 1987)
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DR	Sauer et al., "Primary Structure of the Phage P22 Repressor and its Gene c2", <u>Biochem.</u> , 20:3591-3598 (1981)
DS	Schadel, "Oral Vaccination using Recombinant Bacteria", Semin. Immunol., 2:341-349 (1990)
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D	U	Schweder et al., "Escherichia coli K12 relA Strains as safe Hosts for Expression of Recombinant DNA", Appl. Microbiol. Biotechnol., 42:718-723 (1995)
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D	w	Sites et al., Basic and Clinical Immunology (Lange Medical Books, Los Altos, CA, 1994)
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D	PΥ	Spector and Cubitt, "Starvation-Inducible Ioci of Salmonella typhimurium: Regulation and Roles in Starvation-Survival", Mol. Micro., 6:1467-1476 (1992)
D	Z	Studier et al., "Gene Expression Technology", Methods Enzymol., 185:60-89 (1990)
E	EA	Tacket et al., "Comparison of the Safety and Immununogenicity of Acya ACrp Salmonella typhi Strains in Adult Volunteers", <u>Infect. Immun.</u> , 60:536-541 (1992)
E	ЕВ	Tanabe et al., "Identification of the Promoter Region of the Escherichia coli Major Cold Shock Gene, cspA", J. Bacteriol. 174:3867-3873 (1992)
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E	EH	Vuorio and Vaara, "Mutants carrying conditionally lethal Mutations in Outer Membrane Genes oms A And lir A (ssc) are Phenotypically similar, and oms A is Allelic to fir A", J. Bacteriol., 174(22):7090-7097 (1992)
E	CI	Wijsman, "The characterization of an Alanine Racemase mutant of <i>Escherichia coli</i> ", <u>Genet. Res. Camb.</u> , 20:269-277 (1972)
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F	CL.	Young, "Bacteriophage Lysis: Mechanism and Regulation", Microbiol. Rev., 56:430-481 (1992)
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